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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,870	04/10/2001	Thomas D. Chittenden	104322.147 US5	7819
24395	7590	10/18/2004	EXAMINER SCHULTZ, JAMES	
WILMER CUTLER PICKERING HALE AND DORR LLP THE WILLARD OFFICE BUILDING 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			ART UNIT 1635	
PAPER NUMBER				

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,870

Applicant(s)

CHITTENDEN ET AL.

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 28-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Status of Election/Restrictions***

Applicant's election with traverse of Group I and SEQ ID NO: 36 in the reply filed on July 30, 2003 is acknowledged. However, the restriction requirement of July 1, 2004 inadvertently provided improper directions to choose one sequence if Group I is elected, and a single combination of sequences if Group II were elected. These directions are not considered to be internally consistent with the concepts of the two inventions for the following reasons. Group I is directed to methods of detecting heterodimerization (i.e. the interaction of two different sequences) between any of SEQ ID NOS: 35-41, and thus restriction cannot be to a single sequence in this method, since by definition heterodimerization must be between two different sequences. Therefore, if Group I is elected, drawn to methods of detecting heterodimerization, applicants are directed to elect a single combination of sequences chosen from SEQ ID NOS: 35-41. Alternatively, should Group II be elected, drawn to methods of detecting homodimerization, which by definition is the interaction of two identical sequences, applicants are directed to elect a single sequence chosen from SEQ ID NOS: 35-41.

The restriction requirement of July 1, 2004 is provided below with corrections as discussed above.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 28 and 30-36, drawn to a method of identifying an agent that modulates GD domain mediated heterodimerization, classified in class 435, subclass 6.
- II. Claims 29 and 37-39, drawn to a method of identifying an agent that modulates GD domain mediated homodimerization, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons: inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different modes of operation and different effects. For example, the methods of Group I operate by determining modulation of two different GD domain proteins and have the effect of identifying modulators of heterodimerization, whereas the methods of Group II operate by determining modulations of the same GD domain proteins and have the effect of identifying modulators of homodimerization. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Further Restriction to a Single Nucleotide Sequence

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in claims 28, 29, 32, 34-36, and 39 are subject to restriction. Upon election of a Group from those listed above, Applicant is further required to elect a single combination of nucleotide sequences if Group I is elected, or a single sequence if Group II is elected. In each case, this sequence election will be

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considered to be an election of the corresponding single named GD Domain protein type (or combination thereof (E.g. Bak, Bcl-xl, bax or Bip1a).

The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434). However, due to the enormous search burden placed on the Office for sequence searching and the complex nature of the search and examination of the methods associated with these sequences, one recombinant gene sequence chosen from the claimed sequences of SEQ ID NOS: 35-41 (or one specific combination in the case of Group I) has been determined to be a reasonable number of sequences to be searched, particularly since the search for one sequence is independent and non-coextensive with the search for another. Claims 28, 29, 32, 34-36, and 39 are directed to methods wherein the GD Domain protein can be any of SEQ ID NOS:35- 41 . Each of these sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique amino acid sequence, and each of these protein functions in a distinct fashion, for example, with regard to binding activity. Furthermore, a search of more than one (1) of the sequences claimed in claims 28, 29, 32, 34-36, and 39 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect a single combination of sequence (in

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the case of Group I) or one (1) sequence from claims 28, 29, 32, 34-36, and 39 (in the case of an election of Group II).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

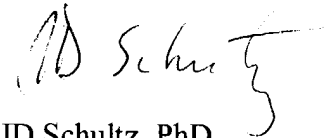
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USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JDS

A handwritten signature in black ink, appearing to read "JD Schultz", with a stylized flourish at the end.

JD Schultz, PhD
Patent Examiner
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